



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances;

Notice of Registration;

Cambrex Charles City, Inc.

By Notice dated September 27, 2013, and published in the Federal Register on October 25, 2013, 78 FR 64017, Cambrex Charles City, Inc., 1205 11<sup>th</sup> Street, Charles City, Iowa 50616, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
4-Anilino-N-phenethyl-4-piperidine (8333)	II

Drug	Schedule
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Alfentanil (9737)	II
Remifentanil (9739)	II

Drug	Schedule
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

No comments or objections have been received. The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cambrex Charles City, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. The DEA has investigated Cambrex Charles City, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is

granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: February 19, 2014.

Joseph T. Rannazzisi,  
Deputy Assistant Administrator,  
Office of Diversion Control,  
Drug Enforcement Administration.

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